DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

3057 '00 APR 24 A10 :33

Mikart, Inc.
Attention: Cerie McDonald
1750 Chattahoochee Ave.
Atlanta, GA 30318

APR 14 2000

Docket No. 99P-2149/CP1

Dear Ms. McDonald:

This is in response to your petition filed on July 2, 1999, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Butalbital, Acetaminophen and Caffeine Tablets and Capsules, 50 mg/500mg/20 mg. The listed drug product to which you refer in your petition is Esgic-Plus® (Butalbital, Acetaminophen and Caffeine Tablets), 50 mg/500 mg/40 mg, manufactured by Mikart, Inc.

Your request involves a change in dosage form (i.e., from tablets to capsules) and in the strength of the caffeine component (i.e., from caffeine 40 mg to caffeine 20 mg) from that of the listed drug product. The changes that you request are the type of changes that are authorized under Section 505(j)(2)(C) of the Act.

This petition was reviewed pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act). Under Section 505(j)(2)(C)(i) of the Act such a petition will be approved unless the Agency finds that investigations must be conducted to show the safety and effectiveness of the proposed drug product, or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug product.

The Agency has determined that your proposed change in the strength for the caffeine component of your proposed drug product raises questions of effectiveness, because the Agency has concluded that the effectiveness of 20 mg of caffeine in the proposed product is in question.[1,2,3] Therefore, FDA is denying the petition under Section 505(j)(2)(C)(i) because investigations are necessary to show the effectiveness of the proposed drug product.

---

1 Refer to section O. Comments on Adjuvants and Corrective Agents of Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Tenative Final Monograph; Notice of Proposed Rulemaking, 53 FR 46204, Nov. 16, 1988.

2 Arch. Intern. Med. – Vol 141, Feb. 23, 1981, p 293-300, Aspirin and Acetaminophen as Constitutents of Analgesic Combinations, William T. Beaver MD

3 Certain Barbiturate-Analgesic Oral Combination Drugs; Drugs for Human Use; Drug Efficacy Study Implementation Amendment, 47 FR 34634, Aug. 10, 1982.

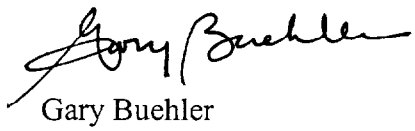
99P-2149

RDNF

If you disagree with our determination concerning the acceptability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR Section 10.20, in the format outlined in Section 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,



Gary Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research